This record is a partial extract of the original cable. The full text of the original cable is not available.

250700Z Apr 05

UNCLAS TAIPEI 001901

SIPDIS

STATE FOR EAP/RSP/TC, PASS AIT/W AND USTR, USTR FOR KI AND FREEMAN

E.O. 12958: N/A
TAGS: ECON ETRD TW ESTH
SUBJECT: DOH DRAFTING REGS FOR TAIWAN'S NATIONAL BLOOD LAW

¶1. AIT met with the Director General of the Bureau of Medical Affairs (BOMA) Hsueh Jiu-yuan and staff April 19 to discuss the status of draft implementing regulations for the National Blood Law passed in December 2004. An initial draft of the regulations has been prepared, AIT/T is preparing and will transmit an informal translation to AIT, State, Commerce, and USTR via unclassified e-mail Hsueh promised that BOMA would meet with all interested stakeholders prior to submitting the draft regulations to the Executive Yuan. A meeting is scheduled for May 13 or 19 to give industry associations the opportunity to propose specific amendments to the regulations.

¶2. Specific questions from industry center on the law's requirement that blood product manufacturers obtain approval from a central competent authority before being allowed to import material from foreign countries; and the requirement that medical facilities prioritize the use of blood preparations manufactured using domestic blood donations. International providers of blood and blood products allege these requirements violate Taiwan,s WTO national treatment commitments.

¶3. Hsueh clarified that the law only requires Taiwan-based manufacturers to prioritize use of domestic blood plasma as a raw material. Only when there is insufficient supply of locally collected blood plasma can firms apply for approval to import blood. Since there are currently no international manufacturers processing blood or blood products in Taiwan, the law does not place a burden on international manufacturers, he said. Hsueh took pains to emphasize that imported blood products need not be sourced from domestic blood plasma. The DOH will be the competent authority to approve imports and will endeavor to make the requirement pro forma, although Hsueh could not say what branch of DOH will shoulder this responsibility.

¶4. When asked how the DOH would enforce the requirement that medical institutions prioritize the use of domestically sourced blood products, Hsueh admitted DOH had no real authority to do so. Instead, he expects DOH will circulate a notice to all medical facilities, informing them of the requirements of the law. Nothing in the law authorizes penalties for failure to prioritize the use of domestic blood products, nor are there any provisions to provide financial incentives to promote the use of domestic products.

¶5. The draft regulations should be submitted to the EY sometime soon after the scheduled meeting with industry associations. Although BOMA characterized this meeting as a public hearing, it will be by invitation only and will not include representatives of individual companies or members of the public. Hsueh expected the regulations would take effect by the beginning of 2006.

¶6. Comment: It was clear during the course of AIT's meeting with BOMA that DOH was eager not to violate WTO principles regarding national treatment. However, BOMA staff drafting the regulations had very little understanding of WTO requirements or how their proposed draft could discriminate against international suppliers of blood plasma raw materials and finished blood products. AIT has contacted US suppliers of blood products active in the Taiwan market to share the draft regulations and advise them of DOH's willingness to meet privately to discuss. End Comment.
PAAL